

**Notice of Allowability****Application No.**

09/613,591

**Applicant(s)**

BOYLE ET AL.

**Examiner**

Regina M. DeBerry

**Art Unit**

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/10/04.
2. ☒ The allowed claim(s) is/are 17, 18, 20-25, 39-42 and 62-64 (renumbered as 1, 2, 5, 3, 4, 6-15, respectively).
3. ☒ The drawings filed on 08 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **EXAMINER'S AMENDMENT/COMMENT**

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for the cancellation of claim 19 and the following Examiner's amendment was given in a telephone interview with Timothy J. Gaul on 17 November 2004.

The specification has been amended as follows:

At page 1, lines 5-11, please replace with the following paragraph:

This application is a continuation-in-part of U.S. Ser. No. 09/457,647, filed December 9, 1999, now abandoned, which is a continuation-in-part of U.S. Ser. No. 09/350,670, filed July 9, 1999, now abandoned, which is a continuation-in-part of U.S. Ser. No. 08/706,945, now U.S. Patent 6,369,027, filed on September 3, 1996, which is continuation-in-part of U.S. Ser. No. 08/577,788, now U.S. Patent 6,613,544, filed December 22, 1995. Each of the foregoing applications is hereby incorporated by reference.

At page 13, lines 28-31, please replace with the following paragraph:

Figure 29A through 29J. Sequence of OPG-Fc. DNA and encoded protein sequences are shown. Restriction sites for various nucleases are noted above the DNA sequence (SEQ ID NO:176 and 177).

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At page 13, line 32-page 14, line 3, please replace with the following paragraph:

Figures 30A-1 through 30B-2. Effects of OPG-Fc during the course of adjuvant arthritis I male Lewis rats. Paws from rats with adjuvant arthritis induced by 0.5mg mycobacteria in oil were analyzed by DEXA for bone mineral density (BMD). Evaluation of BMD, a 29mm X 25mm box was centered at the calcaneus (expt AdA-14 2/99, Amgen nb#22957 p47-49). \* compared to normal, # compared to vehicle P<0.05 Mann-Whitney U test.

At page 14, lines 4-8, please replace with the following paragraph:

Figures 31A and 31B. Combination treatment with OPG-FC and sTNFR-I on Adjuvant Arthritis in Male Lewis Rats. Area under the curve (AUC) for measurement of paw swelling and BMD were measured as described above for Figure 30 and in the examples hereinafter.

The claims have been amended as follows:

- 1X. A method of treating bone loss, which comprises administering an IL-1 inhibitor, a TNF- $\alpha$  inhibitor, and an OPG protein, wherein "OPG protein" refers to a polypeptide comprising conserved residues from residues 22 to 185 of SEQ ID NOS: 121, 123, or 125.

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2 ~~18~~. The method of Claim ~~17~~<sup>1</sup>, wherein the TNF- $\alpha$  inhibitor comprises sTNFR-I, sTNFR-II, an sTNFR fragment, or sTNFR-Fc, wherein "sTNFR" refers to sTNFR-I or sTNFR-II.

19. (Canceled).

13 ~~02~~. The method of Claim ~~17~~<sup>1</sup>, wherein the OPG protein comprises residues 22 to 185 of SEQ ID NO: 121.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

*RMD*

RMD  
11/17/04